

REMARKS

Claims 1-18 are pending and stand rejected. Applicants respectfully request reconsideration of the present application in view of the remarks below.

Claim Amendments

Applicants cancel claims 1-18 and add new claims 19-42. New claim 19 recites a method for producing a plurality of medical test implements that includes steps of folding first and second portions of a handle-forming material toward one another, separating the first and second portions of the handle-forming material, positioning a plurality of test elements, each having a predetermined length, between the first and portions of the handle-forming material such that each test element is spaced apart from one another by a predetermined distance, mechanically mating the first and second portions of the handle-forming material to one another with the plurality of test elements disposed therebetween, and perforating, scoring, or cutting the first and second portions of the handle-forming material to form a plurality of medical test implements, each having a handle and a test element that is adapted to deform when a predetermined load is applied thereto.

Similarly, new independent claim 40 recites a method for manufacturing a plurality of medical test implements that includes the steps of positioning a plurality of test elements, each having a predetermined length, between first and second handle-forming sheets, such that each test element is spaced apart from one another by a predetermined distance, mechanically bonding the first and second handle-forming sheets to one another with the plurality of test elements disposed therebetween, and cutting the bonded first and second handle-forming sheets with the test elements disposed therebetween to form a plurality of medical test implements, each including a handle and a test element.

New independent claims 41 recites a method for manufacturing a plurality of medical test implements that includes the steps of feeding an elongate sheet of a handle-forming material through a machine that is effective to fold and separate the sheet lengthwise into first and second portions, passing the first and second portions through a test element placement machine that is effective to deposit a plurality of test elements, each having a predetermined length, between the first and

portions of the handle-forming material such that each test element is spaced apart from one another by a predetermined distance, mechanically mating the first and second portions of the handle-forming material to one another with the plurality of test elements disposed therebetween, and forming a plurality of medical test implements, each having a handle and a test element, by perforating, scoring, or cutting the first and second portions of the handle-forming material.

Support for new independent claims 19, 40, and 41 can be found throughout the specification, for example, at page 7, line 20 to page 8, line 14, page 9, lines 1-20, page 10, lines 13-17, and page 11, lines 4-9. Dependent claims 20-39, and 42 include subject matter previously presented in original claims 1-18, and thus no new matter is added.

Amendments to the Specification

Applicants amend the specification to correct minor typographical errors. No new matter is added.

Amendments to the Drawings

Applicants submit a replacement sheet for Figure 8 in which reference number "62" is replaced with reference number - - 66 - - . No new matter is added.

Rejection Pursuant to 35 U.S.C. §112

Claims 1-18 are rejected pursuant to 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 1-18 are cancelled, thereby obviating the basis for this rejection. New claims 19-42 do not include the indefinite language referred to by the Examiner.

Rejection Pursuant to 35 U.S.C. §103(a)

Claims 1-18 are rejected pursuant to 35 U.S.C. §103(a) as being obvious over an article entitled "Foot Screening-Care of the Foot in Diabetes" (hereinafter "Foot Screening"), in view of an article entitled "Use of the Semmes-Weinstein 5.07/10 Gram Monofilament: the Long and Short of it," by McGill et al. (hereinafter "McGill"), and U.S. Patent No. 4,807,938 of Weihrauch and/or

the Adhesives Technology Handbook (hereinafter the "Handbook"). Claims 1 and 5-13 are also rejected pursuant to 35 U.S.C. §103(a) as being obvious over U.S. Patent No. 6,113,551 of Isaacs et al. (Isaacs) in view of McGill, U.S. Patent No. 6,207,000 of Schwobel et al. (Schwobel), U.S. Patent No. 3,616,083, and U.S. Patent No. 4,021,289 of Orzelek et al. (Orzelek). The Examiner further rejects claims 2-4 and 14-18 pursuant to 35 U.S.C. §103(a) as being obvious over Isaacs in view of McGill, Schwobel, Mohr, and Orzelek, and further in view of Foot Screening and optionally U.S. Patent No. 3,511,735 of Lindley.

While claims 1-18 are cancelled, thereby obviating the basis for these rejections, Applicants provide the following remarks and submit that new claims 19-42 distinguish over these references, taken alone or in combination.

The Claimed Invention

New independent claim 19 recites a method for making a plurality of medical test implements in which a plurality of test elements, each having a predetermined length, are positioned between first and portions of a handle-forming material such that each test element is spaced apart from one another by a predetermined distance. The first and second portions of the handle-forming material are then mechanically mated to one another with the plurality of test elements disposed therebetween. The mated first and second portions can then be perforated, scored, or cut to form a plurality of medical test implements, each having a handle and a test element that is adapted to deform when a predetermined load is applied thereto.

New independent claim 40 similarly recites a method for manufacturing a plurality of test implements that includes the steps of positioning a plurality of test implements between first and second handle-forming sheets, mechanically bonding the sheets to one another, and cutting the bonded sheets to form a plurality of medical test implements.

New independent claim 41 also recites a method for manufacturing a plurality of medical test implements that includes the steps of feeding an elongate sheet through a machine that is effective to separate the sheet into lengthwise first and second portions, passing the portions through a test element placement machine that deposits a plurality of test elements between the

portions, mechanically mating the portions, and forming a plurality of test implements from the mated portions.

None of the cited references teach or even suggest the methods recited in independent claims 19, 40, and 42.

The Cited References

At the outset, Applicants note that Schwobel, Lindley, Mohr, Weihrauch, and Orzelek are non-analogous art, for reasons discussed below, and thus these references cannot be combined with any of Foot Screening, McGill, the Handbook, and Isaacs. Accordingly, Foot Screening, McGill, the Handbook, and Isaacs are the only relevant references, and none of these references, taken alone or combined, teach or even suggest the present invention. Our remarks regarding each of these references are provided below.

(1) Foot Screening

Foot Screening discloses a method for making LEAP filaments that requires a filament to be adhered between a folded index card to form a single test implement. The index card is used to provide the necessary dimensions of the resulting test implement. Foot Screening does not teach or even suggest positioning a plurality of filaments between a folded material, much less cutting the material to form a plurality of test implements, as required by claims 19, 40, and 41 of the present invention. Foot Screening is specifically limited to forming a single test implement. Accordingly, claims 19-42 distinguish over Foot Screening.

(2) McGill

McGill does not remedy the deficiencies of Foot Screening. McGill is directed to the physical characteristics of monofilaments, and merely teaches cutting a filament to a predetermined length. McGill does not teach or even suggest any method of making a test implement, much less a method of making a plurality of test implements as required by claims 19, 40, and 41. Accordingly, claims 19-42 distinguish over McGill.

(3) *The Handbook*

The Handbook is relied on by the Examiner to disclose the use of heat activatable coatings to bone parts together. Accordingly, the Handbook does not teach or even suggest any method of making a test implement, and therefore the Handbook does not remedy the deficiencies of Foot Screening and/or McGill.

(4) *Isaacs*

Isaacs also fails to teach or even suggest the claimed invention. Isaacs discloses a test implement and method for making the same. As shown in Figure 3, and described at Col. 3, lines 14-49, a single filament is placed on a sheet, an adhesive is applied to the sheet, and the sheet is folded and heated to seal the filament therebetween. Isaacs does not teach or even suggest making a plurality of test implements by placing a plurality of filaments onto a single, folded sheet, and then cutting the sheet to form individual test implements.

Accordingly, none of the references, taken alone or combined, teach or even suggest the present invention. Applicants have provided a novel method for making a plurality of test implements that guarantees quality and diagnostic accuracy, and that is cost-effective. Claims 19-42 therefore distinguish over the art and represent allowable subject matter.

(5) *Non-Analogous References*

As indicated above, Schwobel, Lindley, Mohr, Weihrauch, and Orzelek are non-analogous art, and therefore these references cannot be combined with any of Foot Screening, McGill, the Handbook, and Isaacs. A reference is "analogous" if (1) the reference is within the field of the inventor's endeavor, and if it is not, then (2) the reference must be reasonably pertinent to the particular problem with which the inventor was involved. MPEP 2141.01(a). Schwobel, Lindley, Mohr, Weihrauch, and Orzelek are not within the field of the Applicants' endeavor, and they are certainly not reasonably pertinent to the problem to be solved.

Schwobel discloses a method for making test devices having a capillary tube analytical device for collecting liquid samples. While one of Schwobel's object is to produce these devices

“cheaply, reproducibly, and exactly,” the problem to be solved is to provide a capillary-active zone in the devices. Applicants’, on the other hand, set out to provide a method for manufacturing testing implements for diabetes-related foot problems in such a way to guarantee both their quality and diagnostic accuracy. Because Schwobel is in a different field from the present invention, and it relates to different problems and solves them in a different way, it cannot be used to support the present rejection.

Lindley, which likewise cannot be used to support the present rejection, discloses a method for making shopping bags having handles that solves the problem of providing improved, automatic and continual means to heat seal a pair of handles to plastic bags. A method for attaching a pair of handles to a plastic bag is not relevant to the present invention, and in fact, such a method could not be used with the present invention as Lindley does not provide any techniques for ensuring accuracy, as is required by the present invention. Accordingly, because Lindley is in a different field and it relates to different problems solved in a different way, it cannot be used to support the present rejection.

Mohr discloses a method for making a strip of fasteners for a nail gun or similar device wherein the fasteners are connected to each other using a thin connecting strip coated with a thermoplastic adhesive. Mohr solves the problem of producing strip-shaped sets of fasteners in a fully automatic and continuous operation. Such a method is not relevant to the present invention, and it does not solve the problem of producing accurate, quality test implements. Accordingly, Mohr likewise cannot be relied on to support the present rejection.

The Examiner also cannot rely on Weihrauch to support the present rejection since Weihrauch discloses a process for producing bristles that avoids the formation of loops or eliminates existing loops during processing. While Applicants require straight test elements, Weihrauch’s method for producing bristles without the formation of loops is not reasonably pertinent to the problem to be solved. As previously stated, Applicants set out to provide a method for making test implements in such a way to guarantee both their *quality* and *diagnostic accuracy*. Weihrauch does not provide any such method.

Orzelek is likewise non-analogous and cannot be relied on by the Examiner to support the

present rejection. Orzelek discloses a method for packaging leads used in electronic components that overcomes the problem of an incomplete seal created between the components, and a limited shelf life. This problem, and the method for solving this problem, is not reasonably pertinent to Applicants' endeavor, and therefore Orzelek is non-analogous art.

In sum, Schwobel, Lindley, Mohr, Weihrauch, and Orzelek are not within the field of the Applicants' endeavor, and they are certainly not reasonably pertinent to the particular problem with which Applicants were involved. None of these references provides a solution for mass-producing testing implements for diabetes-related foot problems in such a way to guarantee both their quality and diagnostic accuracy. Applicants have provided a novel method for manufacturing a LEAP testing implement that is not taught or even suggest by the prior art. Prior to the present invention, LEAP testing implements had to be manufactured individually, by hand, to ensure that each test element had a specific length and was placed at a specific location on an adhesive-coated handle.


Applicants further note that even if Schwobel, Lindley, Mohr, Weihrauch, and Orzelek could be considered "analogous," none of these references, taken alone or combined with Foot Screening, McGill, the Handbook, and/or Isaacs, teach or even suggest the present invention since none of these references discloses a method for manufacturing test implements that includes positioning a plurality of filaments between a folded material, and cutting the material to form a plurality of test implements, as required by independent claims 19 and 40. The references also fail to teach or even suggest the method recited in independent claim 41, wherein an elongate sheet is feed through a machine that is effective to separate the sheet into lengthwise first and second portions, the portions are passed through a test element placement machine that deposits a plurality of test elements between the portions, and then the portions are bonded and formed into a plurality of test implements.

Conclusion

In view of the amendments and remarks above, Applicants submit that claims 19-42 are in condition for allowance. In the event that the above amendments and remarks are not deemed to place this case in condition for allowance, an opportunity to interview with the Examiner is requested. Applicants encourage the Examiner to telephone the undersigned upon receipt of this response to discuss any issues that may remain.

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Respectfully submitted,



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